



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Health Resources and Services Administration**

#### **Notice with Request for Comment: Consideration of Adding Metachromatic**

#### **Leukodystrophy to the Recommended Uniform Screening Panel**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice with request for public comment.

**SUMMARY:** HRSA is considering recommending to the Secretary the addition of Metachromatic Leukodystrophy (MLD) to the Recommended Uniform Screening Panel (RUSP). HRSA is providing notice and requesting comments from the public on this potential recommendation. Conditions listed on the RUSP are part of the evidence-informed preventive health guidelines supported by HRSA for infants and children. Non-grandfathered health plans are required to cover screenings included in the HRSA-supported comprehensive guidelines without cost-sharing (e.g., co-payment, co-insurance, etc.). HRSA is particularly interested in comments that address the potential benefit of early screening of MLD within the newborn period, the ability of state newborn screening programs to screen for MLD, and the availability of effective treatments for MLD. In deciding whether to provide recommendations to the Secretary supporting the addition of MLD to the RUSP, HRSA will consider public comments, including evidence-based reports, obtained through this notice.

**DATE:** Submit comments no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** Responses must be submitted electronically to CDR Leticia Manning, MPH, at: [NBSPPrograms@hrsa.gov](mailto:NBSPPrograms@hrsa.gov).

**FOR FURTHER INFORMATION CONTACT:** CDR Leticia Manning, MPH, Newborn Screening Team Lead, Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857 or *NBSPrograms@hrsa.gov*.

**SUPPLEMENTARY INFORMATION:** The information obtained through this notice may help inform HRSA on the benefits of screening for MLD and adding this condition to the RUSP. Of the 56 newborn screening programs in the United States, all states and Puerto Rico currently screen for at least 31 of the 37 core conditions on the RUSP. Some states also screen for additional disorders. Conditions listed on the RUSP are part of the evidence-informed preventive health guidelines supported by HRSA for infants and children. Non-grandfathered health plans are required to cover screenings included in the HRSA-supported comprehensive guidelines without cost-sharing. The Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC), now terminated, was tasked with reviewing available scientific evidence and then making recommendations to the Secretary regarding what conditions should be on the RUSP. When a condition is nominated, ACHDNC determines whether there is sufficient evidence available for early screening and refers it to the ACHDNC's Evidence Review Group (ERG). The ERG is responsible for identifying and assessing all available evidence and summarizing for ACHDNC the strength and effectiveness of the evidence found on the net benefit of screening, the ability of states to screen for the condition, and the availability of effective treatments. The ERG completed an evidence review for MLD. ACHDNC was terminated following the completion of the evidence review for MLD, but prior to making a recommendation on its inclusion in the RUSP or issuing a recommendation to the Secretary.

When drafting responses, consider the data and other information described on the ERG's report summary, and provide input on the suitability of states screening for MLD

within the newborn period. The evidence-based review summary for MLD can be found at <https://www.hrsa.gov/advisory-committees/heritable-disorders>.

**Special Note to Commenters**

This notice is not inviting nominations for other conditions to be added to the RUSP. HRSA is considering potential ways to continue supporting the RUSP and the overall system of newborn screening. In deciding whether to provide a recommendation to the Secretary supporting the addition of MLD to the RUSP, HRSA will consider evidence-based reports and public comments obtained through this notice.

**Maria G. Button,**

*Director, Executive Secretariat.*

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